News

Paragonix Technologies, Inc., Announces European Conformity ("CE") for the SherpaPak™ Cardiac Transport System and SherpaPerfusion™ Cardiac Transport System

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BRAINTREE, Mass.--(EON: Enhanced Online News)--Paragonix Technologies, Inc. today announced European approval for Paragonix SherpaPak™ Cardiac Transport System[1,2] and SherpaPerfusion™ Cardiac Transport System[3,4] for application of a CE mark following review of a Technical File submission by The British Standards Institution (BSI). Paragonix was issued a CE Certificate by BSI for the design and manufacture of organ transportation devices for hearts and kidneys. This includes the Paragonix SherpaPak™ and SherpaPerfusion™ family of products. The SherpaPak™ Cardiac Transport System consists of a single-use, disposable device for the hypothermic static preservation and transport of donor hearts. The SherpaPerfusion™ Cardiac Transport System consists of a single-use, disposable device for hypothermic oxygenated perfusion preservation and transport of donor hearts.

In 2017, over 2,000 donor hearts were transplanted in Europe[5]. In spite of significant advances in surgical technique, tissue typing, and immunosuppression, maintenance of organ quality during transport has largely been overlooked. The current standard of care for donor heart preservation and transportation involves placing a heart in a series of fluid-filled sterile bags that are placed on crushed ice contained within a conventional ice chest. Unfortunately, this leads to temperatures below 2^{o}C which significantly increase the risk of cold injury and frostbite. Additionally, the current standard of care for donor heart transport limits the time an organ can be outside the body. To overcome these limitations and ensure optimal organ health following transportation, Paragonix Technologies has developed the Paragonix Sherpa™ platform of donor heart preservation devices as a powerful new technology ensuring superior organ quality during transport.

"Having followed the extensive research and product development activities at Paragonix Technologies over the past few years, I am impressed by the intuitive designs of both SherpaPak™ and SherpaPerfusion™ Cardiac Transport Systems. They directly address all relevant issues of improving donor heart preservation at hypothermia."

Dr. Steven Tsui, Director of Transplantation & Mechanical Circulatory Support and Consultant Surgeon at the Royal Papworth Hospital, UK, commented "I am excited about the European availability of Paragonix's two innovative donor heart preservation devices. I believe that the SherpaPak™ Cardiac Transport System addresses the shortcomings of current cold storage by improving temperature maintenance and monitoring of the donor heart during transport. As a heart transplant surgeon with over a decade's experience of *ex-vivo* donor heart perfusion, I also welcome the addition of SherpaPerfusion™ Cardiac Transport System to the clinical community, utilizing oxygenated hypothermic perfusion for improved donor heart quality. I look forward to both products entering the clinic."

Dr. Andreas Zuckermann, Director of the Cardiac Transplantation Program at the University of Vienna, Austria, commented, "Having followed the extensive research and product development activities at Paragonix Technologies over the past few years, I am impressed by the intuitive designs of both SherpaPak™ and SherpaPerfusion™ Cardiac Transport Systems. They directly address all relevant issues of improving donor heart preservation at hypothermia." Dr. Zuckermann continued, "We look forward to incorporating both donor heart preservation systems at our transplant center."

Dr. Lisa Anderson, President & COO of Paragonix, said "We are thrilled to have reached this milestone and anticipate significant clinical interest for both SherpaPak™ and SherpaPerfusion™ Cardiac Transport Systems. Following our commercial launch of SherpaPak™ in the United States, we look forward to introducing our novel donor heart preservation devices to transplant centers across Europe."

Previous Announcements
Paragonix previously announced August 8, 2017 Extension of Product Portfolio with the Addition of SherpaPak™ Lung Transport System.

Paragonix previously announced April 24, 2017 Presentation of the SherpaPak™ Organ Transport Systems at the American Transplant Congress (ATC) (Chicago, April 29 – May 3, 2017).

Paragonix previously announced March 27, 2017 Presentation of the SherpaPak™ Organ Transport Systems and SherpaPerfusion™ Cardiac Transport System at the 37th Annual Meeting of the International Society for Heart and Lung Transplantation (San Diego, 5 – 8 April 2017).

Paragonix previously announced February 7, 2017 an exclusive distribution agreement with MBA Medical to market Paragonix Technologies' SherpaPak™ Cardiac and Kidney Transport Systems, in the Southern United States.

Paragonix previously announced January 9, 2017 a Presentation of the SherpaPak™ Organ Transport Systems during the ASTS 17th Annual State of the Art Winter Symposium January 26 to 29, 2017 in Miami, FL.

Paragonix previously announced January 4, 2017 an exclusive supply agreement with Sanbor Medical for the Manufacture and Assembly of SherpaPak™ Organ Transport Systems.

About the CE Mark
The CE mark (*Conformité Européenne*, meaning "European Conformity,"[6] formerly EC mark[7]) according to the European Medical Directive (MDD) is a mandatory conformity mark for medical devices placed on the market in the European Economic Area (EEA). With the CE marking on a medical device, the manufacturer ensures that the product conforms to the essential requirements of the applicable EC medical device directives.[8]

About Dr. Steven Tsui
Mr Tsui graduated from the University of Cambridge and underwent cardiothoracic surgical training in Cambridge, Oxford and Duke University Medical School, USA. He was appointed Consultant Cardiothoracic Surgeon at Papworth Hospital in 1998 where he is the Director of Transplantation & Mechanical Circulatory Support. His research interests include donor optimisation and ex-vivo donor organ perfusion. He is Chairman of the Cardiothoracic Advisory Group at NHS Blood & Transplant (NHSBT), UK and Chairman of the Specialty Training Committee for Cardiothoracic Surgery in Health Education East of England.

About Dr. Andreas Zuckermann
Dr. Andreas Zuckermann, M.D. is a Staff Surgeon in the Department of Cardiothoracic Surgery and Director of the Cardiac Transplantation Program at the University of Vienna in Austria. Dr. Zuckermann is also a Director at the International Society for Heart and Lung Transplantation.

About the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System
Currently, the availability of heart and lung transplantation is governed by the "ischemic time", that being, the elapsed time from heart donation to recipient implantation. According to The International Society Of Heart and Lung Transplantation ("ISHLT") guidelines[9] for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours[10,11], limiting the distance available to transport a donor heart. Paragonix SherpaPak™ Cardiac Transport System is fully disposable, eliminating problems associated with maintenance, device transport and contamination. The Paragonix SherpaPerfusion™ Cardiac Transport System combines innovative oxygenated perfusion of organs and safe organ storage with the ultimate goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts.

About the Heart Transplantation Market
Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure[12]. With over 6.5 million Americans currently diagnosed with heart failure (HF)[13], 10% of which are diagnosed with end-stage heart failure[14], there is a persistent need to provide end-stage heart failure support to this expanding population. Estimates of the prevalence of symptomatic HF in the general European population are similar to those in the United States[15]. The annual US economic burden of treating heart failure exceeds $34.4 billion[16], over 50% of which is due to the cost of hospitalization[17]. The financial demands associated with transplantation are considerable. The estimated first year costs for heart transplant are $997,700, and subsequent annual costs can easily exceed $30,000[18]. In the United States, around 30,000 people die annually from end-stage heart disease. As of February 2018, 3,990 patients in the United States are on the waiting list for a heart transplant[19] and close to 4,000 patients in Europe are on the waiting list for a heart transplant every year[20]. In 2017, 3,244 patients in the United States[21] and over 2,000 European patients received a live-saving heart transplant[19]. These data, however, only seem to represent the tip of the iceberg. Assuming that up to 157,000 people with end-stage heart failure are candidates for transplantation[22], maximization of donor organ utilization has enormous potential in cardiac transplantation.

About Paragonix Technologies, Inc.
Based in Massachusetts and founded in 2010, Paragonix Technologies, Inc., is a privately held medical device company innovating the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System, a novel, single-use organ preservation device to improve donor organ quality. Paragonix has established a pipeline of donor organ transport devices that address the current donor organ shortage by maximizing donor organ utilization, improving donor organ quality and extending donor organ transport throughout the entire United States.

[1] The SherpaPak™ Cardiac Transport System is protected by patents, both issued and pending.

[2] The SherpaPak™ Cardiac Transport System has received FDA 510(k) pre-market clearance for heart storage and transport.

[3] The SherpaPerfusion™ Cardiac Transport System is protected by patents, both issued and pending.

[4] The SherpaPerfusion™ Cardiac Transport System is not approved for sale in the United States at this time.

[5] http://www.transplant-observatory.org

[6] http://ec.europa.eu/enterprise/faq/index_en.htm#09012624859cd715

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0068:en:HTML

[8] http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/faq/index_en.htm

[9] ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the Heart Transplant Recipient (Aug. 4, 2010)

[10] J Heart Lung Transplant 2001; 20(2):212.

[11] J Am Coll Cardiol 2004; 43(9):1553-1561.

[12] Datamonitor senior cardiovascular analyst Dr. Sergey Ishin. “Cardiac transplantation continues to be the gold standard for the treatment of end-stage heart failure. However, the number of potential transplants far exceeds the number of donors.” http://about.datamonitor.com/media/archives/314

[13] http://newsroom.heart.org/news/latest-statistics-show-heart-failure-on-the-rise;-cardiovascular-diseases-remain-leading-killer

[14] http://www.heart.org/HEARTORG/Conditions/HeartFailure/LivingWithHeartFailureAndAdvancedHF/Advanced-Heart-Failure_UCM_441925_Article.jsp#.WosY7GNLPjI

[15] http://about.datamonitor.com/media/archives/314

[16] Circulation 2011;123(8):933-944

[17] Circulation 2007;115(5)

[18] http://www.transplantliving.org

[19] http://optn.transplant.hrsa.gov

[20] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20141126_factsfigures_en.pdf

[21] https://unos.org/data/transplant-trends/#transplants_by_organ_type+year+2017

[22] J Heart Lung Transplant 2011;30:1078-94

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Recent Stories

August 08, 2017
Paragonix Technologies Inc. Announces Extension of Product Portfolio with the Addition of SherpaPak™ Lung Transport System
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